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 November 9, 2007

Dr. Barbara Shane
 Executive Secretary for the NTP BSC
 NTP Liaison and Scientific Review Office
 National Institute of Environmental Health Sciences
 PO Box 12233, MD A3-01
 Research Triangle Park, NC 27709

Re: Dec. 6, 2007; National Toxicology Program (NTP) Meeting of the NTP Board of Scientific Counselors: Written Public Comments Concerning the NTP Study Plans for Mold

Dear Dr. Shane,

I am writing to you as Director of *The Center for School Mold Help* (SMH), a national, educational, 501c3 nonprofit. SMH seeks to improve the public health by providing comprehensive, science-based public information, research and resources focusing on school mold prevention and solutions, primarily through our website, located at www.schoolmoldhelp.org. I appreciate the opportunity to provide Public Comments.

Each year, our organization learns of and interacts with thousands of American school communities with extensive school dampness, mold problems, and clusters of serious illnesses in these school workers and students. Many of these buildings are tested, with toxin-producing molds like *stachybotrys* and *aspergillus niger* commonly found as a result of long-standing leaks and moisture intrusion. Most of these schools receive little or no meaningful local, state or federal intervention for these problems and, as a result, remain unhealthy vectors of disease for many decades. *Over time, we believe these damp school buildings to be causing widespread, but preventable, serious and chronic diseases in the American population.*

A large and growing body of literature points to inflammation and infection, with related illnesses, such as respiratory, immune-system, neurological, and skin disease, deriving from indoor air quality problems, dampness, and resulting biological building contaminants. The World Health Organization, Centers for Disease Control, Environmental Protection Agency, Institute of Medicine, National Institute of Occupational Safety and Health, OSHA, the public health sector, and all credible researchers are on record agreeing that dampness and mold are a public health threat and are associated with respiratory disease in previously healthy children (IOM, 2004), having major economic implications (Public health and economic impact of dampness and mold, Fisk et al, 2007). As just one indicator of enormous proportion, “Nearly 1 out of 5 (18.9%) high school students reported lifetime (diagnosis of) asthma.” (CDC, Youth

Risk Behavior Survey, Self-Reported Asthma Among High School Students, United States, 2003, MMWR, August, 2005).

Yet, the reason that damp, moldy schools are not provided with meaningful help from our public health and government sectors is said to be the lack of data about the effects of the biological agents found in “damp buildings”. Specifically, we are told that there are no standards for mold exposure, as no dose-response relationship has been established in studies. We agree with the World Health Organization and other public health authorities that this is an extremely complex undertaking, due to suspected individual, innate responses and multiple-contaminant factors.

Amidst a growing national concern related to mold problems in our nation’s buildings, the Centers for Disease Control and Prevention (CDC) asked the Institute of Medicine to convene a committee of experts, charged with conducting “a comprehensive review of the scientific literature regarding the relationship between damp or moldy indoor environments and the manifestation of adverse health effects, particularly respiratory and allergic symptoms...[focusing] on the non-infectious health effects of fungi, including allergens, mycotoxins and other biologically active products...[making] recommendations or suggest[ing] guidelines for public health interventions and for future basic science, clinical, and public health research in these areas”(IOM, *Damp Indoor Spaces and Health*, 2004, p.2).

In its subsequent 2004 meta-analysis of the literature, called *Damp Indoor Spaces and Health*, the Institute of Medicine concluded that *excessive indoor dampness is a public health problem* (IOM, *Damp Indoor Spaces and Health*, 2004, p.311) and that:

“... there is insufficient information on which to base quantitative recommendations for either the appropriate level of dampness reduction or the “safe” level of exposure to dampness-related agents. The relationship between dampness or particular dampness-related agents and health effects is sometimes unclear and in many cases indirect. Questions of exposure and dose have not, by and large, been resolved (see Chapters 3 and 4). An additional challenge is posed by the fact that it is not possible to objectively rank dampness-related health problems within the larger context of threats to the public’s health. As the report notes, there is insufficient information available to confidently quantify the overall magnitude of the risk resulting from exposures in damp indoor environments” (IOM, *Damp Indoor Spaces and Health*, 2004, p. 314).

Regarding The Public Health Response (Ch. 7), the IOM concludes:

“Among the factors hindering the development of standards are uncertainties over which dampness-related exposures and at what exposure levels may be harmful and limitations associated with all the established means of exposure measurement. Qualitative indicators of the presence of mold also have limitations.”(IOM, *Damp Indoor Spaces and Health*, 2004, p.317)

The multiple biological contaminants found in damp buildings include bacteria, molds, and mildew, listed as indoor air pollutants. (EPA, An Intro to Indoor Air Quality) (<http://www.epa.gov/iaq/biologic.html>) with dampness causing “enhanced growth of fungi and other microbial agents” (IOM, Damp Indoor Spaces and Health, 2004, p.4). These include biologicals of microbial origin, such as structural components of fungal and bacterial cells ... products as microbial volatile organic compounds (MVOCs) and mycotoxins”(IOM, p.5), with constituents of microorganisms—... endotoxins, $\alpha(1\rightarrow3)$ -glucans, fungal extracellular polysaccharides, fungal spores, and other particles and emissions of microbial origin (IOM, p.6).

With regard to the *Toxic Effects of Fungi and Bacteria*, the IOM states: “Research reviewed in [Chapter 4](#) shows that molds that can produce mycotoxins under the appropriate environmental and competitive conditions can and do grow indoors. Damp indoor spaces may also facilitate the growth of bacteria that can have toxic and inflammatory effects. Little information exists on the toxic potential of chemical releases resulting from dampness-related degradation of building materials, furniture, and the like.

In vitro and in vivo studies have demonstrated adverse effects—including immunotoxic, neurologic, respiratory, and dermal responses—after exposure to specific toxins, bacteria, molds, or their products. Such studies have established that exposure to microbial toxins can occur via inhalation and dermal exposure and through ingestion of contaminated food. Animal studies provide information on the potency of many toxins isolated from environmental samples and substrates from damp buildings, but the doses of such toxins required to cause adverse health effects in humans have not been determined. In vitro and in vivo research on *Stachybotrys chartarum* suggests that effects in humans may be biologically plausible, although this observation requires validation from more extensive research before conclusions can be drawn.

The committee ... recommends that *animal studies be initiated to evaluate the effects of long-term (chronic) exposures to mycotoxins via inhalation*. Such studies should establish dose-response, lowest-observed-adverse-effect levels, and no-observed-adverse-effect levels for identified toxicologic endpoints in order to generate information for risk assessment that is not available from presently-available studies of acute, high-level exposures.” (IOM, Damp Indoor Spaces and Health, 2004, p.7-8)

It is universally agreed, among all informed health authorities that there is an urgent need to study further the toxic and possibly synergistic effects of the multiple biological contaminants found in damp buildings, including molds - their particles and emissions. While the complications of multiple contaminants and their effects are acknowledged, it is imperative to learn how these biological agents and their toxins can impact human health with short and long-term exposures, such as would be seen in school and other buildings. Studies related to ingestion have proven that many microbial emissions of

molds are highly carcinogenic – and indeed, we hear of the development of cancers in these moldy school occupants, with some reports of a high mortality rate for those who occupied some of these rooms, often dying within a short time, like several years – but the route of exposure seems to be inhalation and dermal in these moldy buildings. It is well known that there is a dearth of information, currently, about the specific toxic effects of inhalation and dermal exposure, in the literature. This gap in knowledge is contributing to the lack of informed and meaningful action in addressing moldy school buildings and thus, is causing the exposure to a health threat that can ultimately impact every American child and family.

The National Toxicology Program is charged with identifying and selecting for study “chemicals and other substances for which sufficient information is not available to adequately evaluate potential human health hazards”, including:

1. “Substances judged to have high concern as a possible public health hazard based on the extent of human exposure and/or suspicion of toxicity.
2. Substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, e.g. by facilitating cross-species extrapolation or evaluating dose-response relationships.

Input is also solicited regarding the nomination of studies that ... address mechanisms of toxicity, or fill significant gaps in the knowledge of the toxicity of classes of chemical, biological, or physical substances. Increased efforts continue to be focused on:

1. Improving the quality of the nominations of chemicals, environmental agents, or issues for study so that public health and regulatory needs are addressed.
2. Broadening the base and diversity of nominating organizations and individuals.
3. Increasing nominations for studying toxicological endpoints in addition to carcinogenesis.”

(Nominations to the Testing Program, NTP)

The Center for School Mold Help is very pleased that mold has been selected as a topic of discussion in the upcoming meeting of December 6, 2007 of the NTP Board of Scientific Counselors.

On behalf of *The Center for School Mold Help*, and those who wish to maintain their health while working or learning, I ask that the NTP select for study suspected or known toxic building fungi and microbial fungal agents and emissions. This would especially include *stachybotrys*, and toxin-producing species of *aspergillus* and *penicillium*,

trichothecene mycotoxins, and MVOC's, as well as other common molds and their elements, found in damp school buildings.

Types of studies involving mold that *The Center for School Mold Help* suggests are:

For building fungi and their elements that are cytotoxic, or suspected to be:

Study:

1. Determine whether the trichothecenes produced by *Stachybotrys chartarum* growing on building material can move thru the air and be inhaled by experimental animals in sufficient concentrations to cause disease or death.
2. Innate immune-responses to(mold) fungi and fungal elements
3. Whether or not a dose response is an appropriate model as it was not valid in dealing with other inhalation problems from smoking and many chemicals
4. Genetic susceptibility considerations in looking at dose-responses or exposures
5. Toxicity for children, specifically and include those with susceptibilities -- as well as toxicity for adults with and without susceptibilities
6. Mold-induced inflammation and relationships for all mold-induced inflammatory illnesses, including cancers
7. Using animal studies that would most closely mirror the human physical condition

The above types of mold research have been noted as significant gaps, continuously, for the past decade. This has hampered the development of informed public policy and law, and is now of the most urgent priority to maintain the public health. We ask that the NTP help close these gaps with the above areas strongly considered for study.

Thank you for the opportunity to present these comments and requests.

Sincerely,

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